

**Development of the NASA/Baylor Axial Flow Pump for
Ventricular Support
Revision B
Phase 1 Proposal of Three Phase Study**

September 1, 1993 through August 31, 1994

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Copy of: In vitro performance of the Baylor/NASA axial flow pump. *Artificial Organs* (17)7:609-613, 1993. Damm G, Mizuguchi K, Orime Y, Bozeman R, Akkerman J, Aber G, Svejksky P, Takatani S, Nosé Y, Noon GP, DeBakey ME.

1.0 Introduction

The development of a mechanical pump to assist or replace heart function as a means of maintaining circulation in patients with irreversible cardiac failure has engaged the interest of investigators including ourselves for several decades. Our artificial heart team after initial attempts to devise a means of total cardiac replacement turned its primary concern toward the development of a pump for support of the left ventricle, i.e., a left ventricular assist device (LVAD).^{1,2,3}

The left ventricular by-pass pump which we designed for this purpose was used in animals for two years to prove its efficacy and safety.⁴ On this basis, we began its clinical application in patients who were critically ill with heart failure resulting from valvular heart disease. Following operation for valve replacement, these patients required temporary support. Utilization of the LVAD provided support until the heart recovered adequate function.

The first clinically successful use of our LVAD was performed in a 37 year old woman with severe manifestations of aortic and mitral valve insufficiency.⁵ The operation was performed on August 8, 1966. Following replacement of the aortic and mitral valves by means of prosthetic ball valves, it became apparent that this patient could not be weaned from the cardiopulmonary by pass pump owing to heart failure, and the LVAD was installed. With a flow rate of about 1500 cc per minute by the LVAD, it became possible to restore cardiac function to a satisfactory level and remove the cardiopulmonary by pass pump. The LVAD was used to support the patients cardiac function over the next 10 days and at the end of this period, test of cardiac function showed that the heart had completely recovered and the LVAD was removed. The patient was discharge from the hospital about 10 ten days later and subsequently returned to her normal occupation as a hair dresser.

Based upon the technology assessment report from the Institute of Medicine, by early next century, 25,000 to 60,000 patients annually⁶ will require circulatory support by a Left Ventricular Assist Device (LVAD) as a life support system for heart failure. If we include circulatory crippled patients, this number increases to 150,000.⁷ Currently, the only means of circulatory support is with the use of large, complex, and expensive pulsatile LVAD's. Both Thermo Cardiosystems Inc. (TCI) in Boston and Novacor Baxter Travenol Inc. in San Francisco have developed a reliable, safe and effective pulsatile LVAD which provides over one year of circulatory support. As mentioned however, these devices are extremely expensive, and cost approximately \$50,000 for each unit. Thus, the currently available LVADs are not applicable for use on a large population as described above due to financial limitations.

The NASA/Baylor axial pump is small, simple and easy to apply either as an implant in the chest or outside the body with blood flow through simple access cannulae. The control and activation systems are also simple and guaranteed for long term reliable operation. As this device does not require valves or a compliance chamber, it is projected that it can be manufactured for between \$2,000 and \$5,000. Due to the reduced cost and easier clinical application, widespread clinical use is expected with this device.

The principle investigator's team at Baylor College of Medicine, has utilized extra-corporeal non-pulsatile centrifugal pumps for circulatory assist in bridge-to-transplant and post cardiectomy cardiac failure patients in over 150 cases. We have demonstrated excellent clinical results compared to expensive pulsatile products. Contrary to the belief that pulsatile flow is needed for circulatory assist devices, it is our opinion that a non-pulsatile pump and flow will do satisfactorily as a LVAD. Unfortunately, currently available non-pulsatile pumps have a limited life typically for two to six days. It is mandatory to develop a non-pulsatile pump with a longer operating life.

Another motivation for the development of a simple LVAD system is the reduction of available donor hearts. In the past, approximately 2000 heart transplants were performed annually in the United States. In the future, it is expected that less transplants will be performed each year, regardless of the search for donors which includes an expanding criteria for acceptance.

In order to develop a simple and inexpensive LVAD (one having a longer operating life), we have relied on NASA with its engineering expertise and long term experience in rocket engine design. Here at Baylor College of Medicine/Department of Surgery, implantation of LVADs has been performed since the initial surgery by Dr. DeBakey in 1966. We have many experienced and talented medical (both research and clinical) and engineering personnel with the expertise to develop various cardiac prostheses. Combining the best engineering team at NASA with the skilled medical personnel at Baylor, will guarantee success for this program.

1.1 Specific Aims

Together with engineers from NASA/Johnson Space Center, Michael DeBakey, M.D., Chancellor of Baylor College of Medicine, assisted by Mr. George Damm (M.S., Electrical Engineer, Research Associate, Department of Surgery), Kazumi Mizuguchi, M.D. (Research Instructor, Dept. of Surgery) and co-investigators, is proposing to continue the development and evaluation of an implantable, miniature axial flow pump designed for ventricular assist for more than three months duration. This axial pump is small enough to be implanted inside the ventricle; however, the intention is to implant it inside the chest between the left ventricle and aorta.

This 5 L/min miniature pump is capable of operating thrombus-free and without trauma to the blood in bridge-to-heart transplant patients and patients requiring permanent circulatory assist devices. The impeller of the pump has permanent magnets embedded within the six blades and is activated magnetically by the stator which is outside the blood chamber. Basic studies to design this device without magnetic suspension and activation have already been conducted.^{8,9} In addition, an implantable unit with magnets in the impeller blades has been constructed and tested in vitro and in preliminary in vivo studies.¹⁰

Throughout this proposed program, the objective is to develop a clinically applicable axial pump. In vitro hydrodynamic performance studies will be performed to verify its pumping capabilities of approximately 5 L/min against a total pressure head of 100 mm Hg. The anti-traumatic feature of the pump will be studied using human and bovine blood in the Baylor hemolysis test circuit.¹¹ The goal of these studies is to achieve an Index of Hemolysis of less than the currently available

Hemopump¹² (0.04-0.06 g of liberated Hemoglobin/100 L of blood flow). With this level of hemolysis, patients will not develop a free plasma-hemoglobin level higher than 5 mg/dl. This level is considered to be normal. Accelerated endurance studies of the pump will be conducted for longer than three-months and an evaluation made on its parts' wear characteristics.¹³ Surgical feasibility studies in calves will also be attempted. These in vivo implant studies will be used to evaluate and improve both the antithrombogenic nature of the pump and ability of the pumps bearings to operate in blood.

1.2 Project Background

1.2.1 Introduction

In 1984, Mr. David Saucier, Manager Artemis Project, of NASA/Johnson Space Center, received a heart transplantation by Dr. George Noon at the Methodist Hospital. Contrary to his condition prior to his heart transplantation, he was completely rehabilitated and is now participating as a full-time engineer at NASA. Realizing the importance of a heart transplantation and circulatory assist devices, he approached Dr. Noon and Dr. Michael E. DeBakey approximately four years ago, both who were interested in developing an artificial heart or a circulatory assist pump.

Dr. DeBakey suggested to him that a small, implantable axial LVAD was needed because it has wide clinical needs.¹⁴ Since that time, Mr. Saucier has assembled a team of NASA engineers to develop an implantable axial flow pump.

Since the 1970s, Dr. Blackshear's group of Minnesota¹⁵, Dr. Nose's group of Cleveland¹⁶, and Dr. DeBakey's group of Houston¹⁷ have been actively involved in this field of non-pulsatile pump development. Currently it is well accepted that a non-pulsatile pump will sustain human life without any negative physiological effects.

1.2.2 A Two Week Pump

The centrifugal pump is currently replacing ~~Dr. DeBakey's roller pump~~ *being used in conjunction with the heart-lung machine* for open heart surgery. Currently, over 120,000 of these types of pumps are used annually.¹⁸ Unfortunately, this type of pump is only operational for two days. Efforts to extend the life of this type of pump to two weeks or longer are being attempted in the Department of Surgery, Baylor College of Medicine. After almost three years of efforts, the Nikkiso/Baylor pump is currently well-developed and awaiting FDA approval.¹⁹ This pump can be used not only for standard cardiopulmonary bypasses, but also for post-cardiotomy cardiac failure patients (typically required for four to six days) and extra-corporeal membrane oxygenator procedures (ECMO, typically 10 days to two weeks). It is expected that approximately 600,000 such patients require this type of device. The reason that this type of pump has a limited life is very simple. This pump requires a shaft to hold an impeller and an external seal as it is driven by an external motor. This seal promotes blood clotting and results in the shaft freezing, thus limiting its life. A special impeller design and a

water purge system were incorporated in the Nikkiso/Baylor pump to extend its life from two days to two weeks.

1.2.3 A One-Month Pump

Efforts to eliminate this shaft are continued. Dr. DeBakey's team was also working in this area of research.²⁰ The concept of this approach is to eliminate the shaft and replace it with a pivot bearing. The impeller of the pump rotates on this bottom pivot bearing, like a top. Utilizing a seed program fund which was available in the Department of Surgery, Dr. DeBakey and his associates developed a prototype gyro pump and demonstrated its feasibility (Baylor Gyro Pump).²⁰ Currently, this program, funded by Kyocera Corporation of Japan²¹, is in Phase II of the development program. The intended goal is to commercialize this pump and to extend its life for one to three months duration. It is expected that 3% to 5% of the above mentioned patient population requires this type of pump. Unfortunately, it is expected that the life of a gyro pump will also be limited to less than three months due to insufficient washout of the blood at the bottom of the impeller.

1.2.4 A Three Month Pump

In the past, circulatory assist devices required for bridge-to-transplantation were typically used for less than one month. The gyro pump was intended for this type of application. Unfortunately, the waiting time for a heart transplantation with a cardiac prostheses has been extended to an average of three months.¹⁴ In addition, it is generally believed that if the patient waits more than three months with a cardiac prosthesis, the outcome of a heart transplantation would be proven to be much better. Recovery time is shorter and complications are fewer compared to the group of patients with short-term support devices. As indicated in the introduction of this proposal, if this device proves to be effective for over three months, approximately 150,000 patients will be benefited. Currently, the main stream of cardiac prostheses for this group of patients is implantable pulsatile ventricular assist pumps.²² Although they are effective, the cost involved is extremely high, at least ten times higher than that of a non-pulsatile pump. In addition, pulsatile VADs are large, displacing 300 to 400 cc compared to approximately 15 cc for our axial flow pump. Implantation of this type of device is also more complicated. Recently, Dr. Richard K. Wampler of Nimbus, Inc., developed a small percutaneously insertable ventricular assist device (VAD).¹¹ This axial pump is small enough to be inserted from a peripheral artery; however, its flow is restricted to less than 3 L/min. If this type of axial pump with a 5 L/min pumping capacity is available, then it would serve great clinical needs. Currently, several groups in the U.S.A. are trying to develop such a device. The Nimbus pump is operated by a flexible cable. The NASA/Baylor pump intends to use a magnetic drive to rotate the impeller and possibly magnetic suspension to stabilize it. It is small enough to be implantable either inside the arterial system or a ventricle. The concept of magnetic suspension is not new²³, however, it is technically difficult. To date, there is no single practical ventricular assist pump based upon this principle. However, a magnetic drive is easier to achieve with currently available technology using NASA engineering talent.

1.3 NASA/Baylor Axial Flow Pump

In August of 1992, a NASA/Baylor team, headed by Dr. DeBakey, and assisted by George Damm, M.S., and Kazumi Mizuguchi, M.D., at Baylor, decided to investigate the hemolytic properties of the axial pump using a step-by-step approach. It was revealed that critical parameters must be defined in developing an atraumatic and anti-thrombogenic pump. Departmental seed money was used for these feasibility studies. The NASA team contributed to the design of this axial pump. After approximately six months of efforts, all the necessary parameters were defined, and now the design of this axial pump was finalized.^{8,9}

In February of 1993, an initial NASA investment of \$210,000 was made to continue the work done by the NASA/Baylor team. With these moneys, additional hemolysis characterization was performed as well as endurance testing, hydraulic performance testing and initial in vivo implantation studies. With further funding, the rapid progress and pace of these studies will continue. Thus, this proposal is made. Mr. Damm (Electronics Engineer) and Dr. Mizuguchi (Research Instructor) are assisted by Dr. Yukihiro Orime, M.D. Ph.D., (Research Assistant Professor, Chief of Medical Staff-Research Laboratory) Dr. Kimitaka Tasai, M.D. Ph.D., (Research Instructor), Dr. Takatsugu Shimono, M.D. Ph.D., (Research Instructor), Dr. Setsuo Takatani, Ph.D., (Research Associate Professor), Dr. Yukihiro Nose M.D., Ph.D., (Professor of Surgery, Research), Dr. George P. Noon M.D., (Professor of Surgery, Clinical). The NASA team is comprised of Messrs. Richard Bozeman (Electrical Engineer), Jim Akkerman (Mechanical Engineer), Greg Aber (Propulsion Engineer), Paul Svejowsky (Lockheed Staff Engineer), Jim Bacak (Machinist) and David Saucier (Mechanical Engineer).

2.0 Progress Report of Feasibility Study Period (Feb. 1993 through Sept 1993)

NASA funding of the NASA/Baylor Axial Flow VAD program began on February 8, 1993. The initial amount of \$210,000 has been applied towards the continued progress of the various aspects of the axial pump development. Prior to the beginning of this funding period, a prototype axial pump model was used to determine optimal pump parameters to minimize hemolysis caused by pumping blood. During the current funding term (February 1993 through September 1993), an implantable model has been developed using the optimal pump parameters determined from studies using the pump prototype (see Figures 1 and 2). Both the pump overall efficiency and its atraumatic nature have been steadily improved and continued progress is expected.

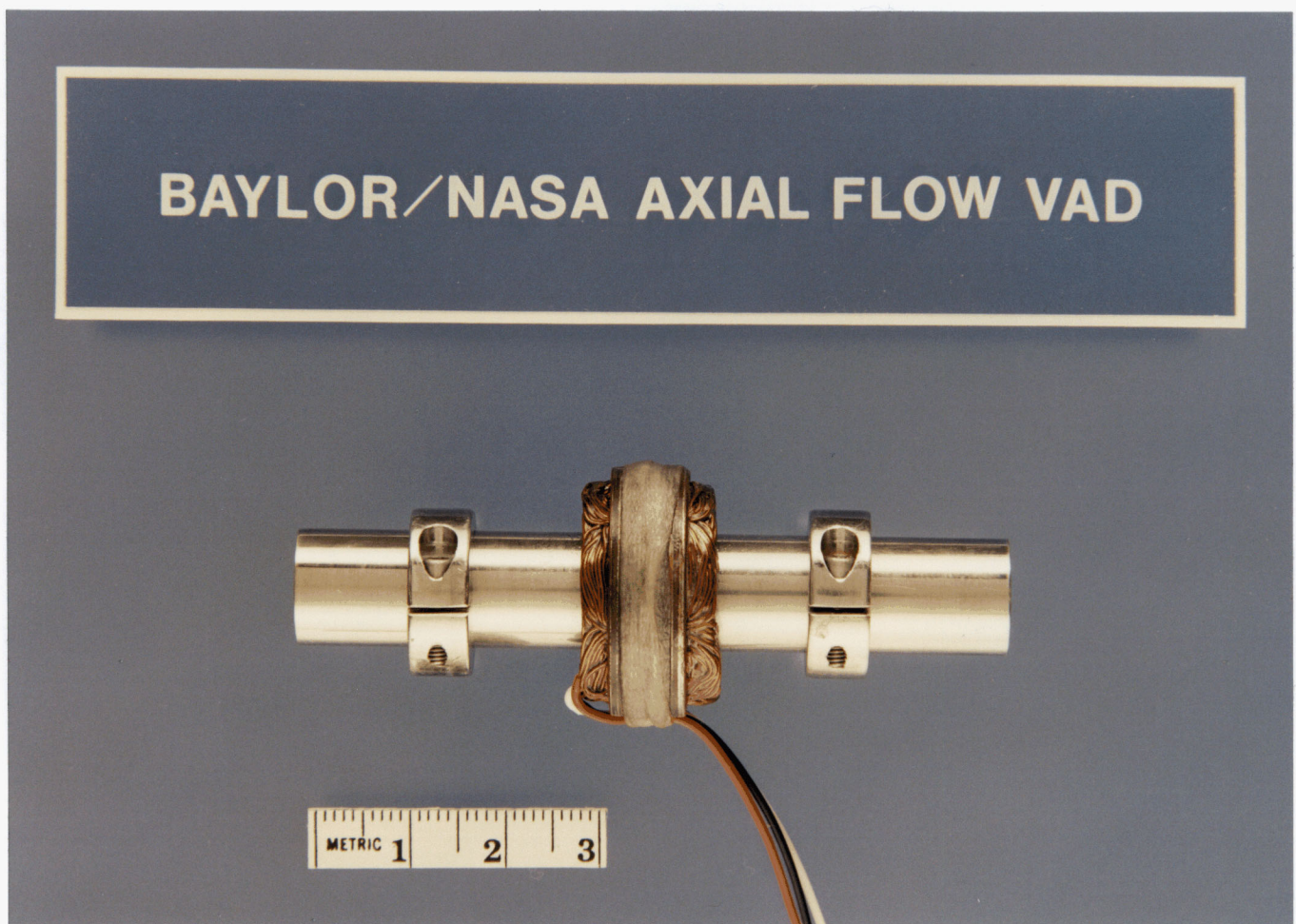


Figure1. Photograph of assembled NASA/Baylor Axial Flow pump

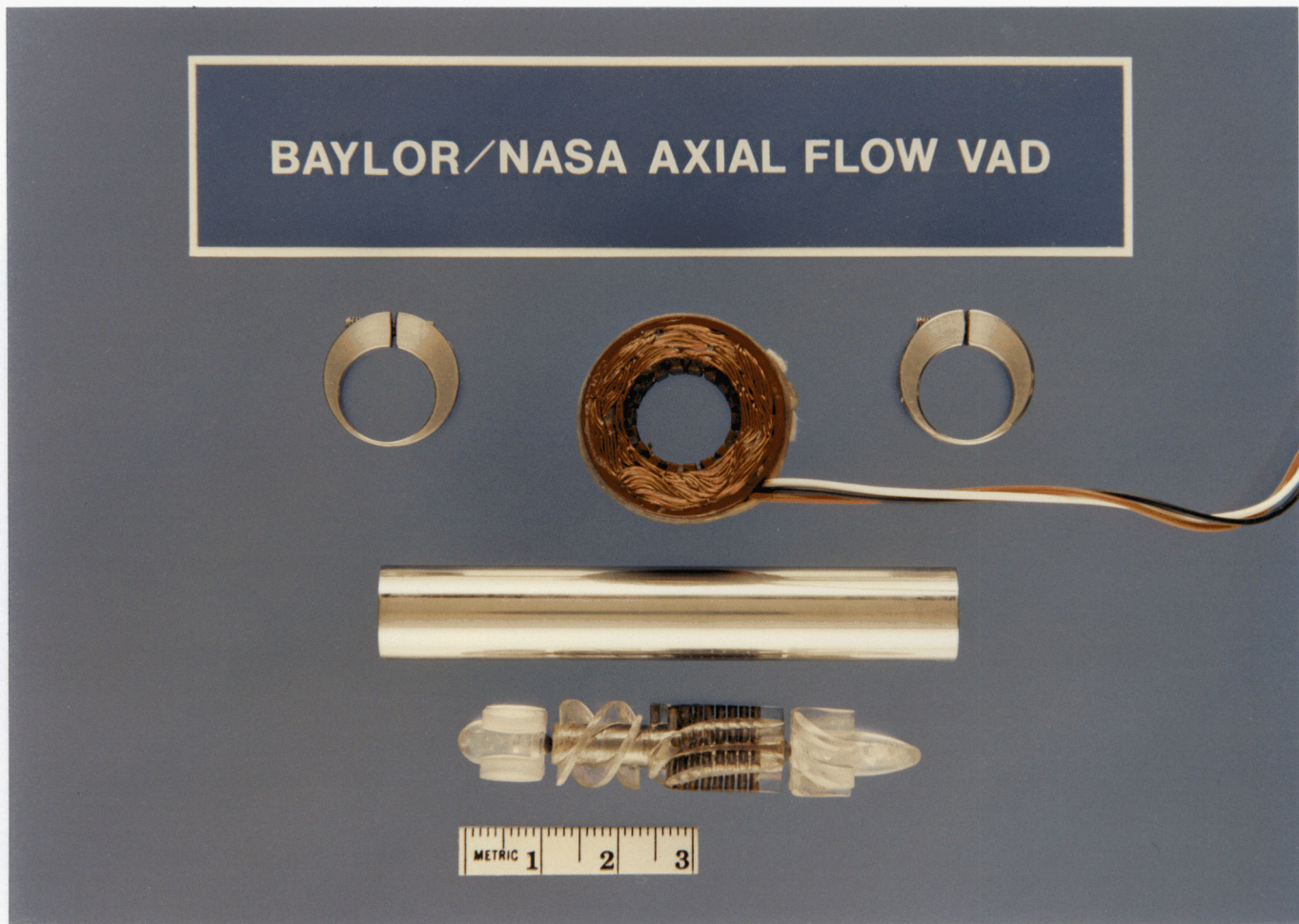


Figure 2. Photograph, exploded view of NASA/Baylor Axial Flow Pump

2.1 Design and Fabrication

The implantable axial pump model has magnets embedded in the impeller blades. The impeller is suspended in a flow tube between 2 sets of jewel bearings. Outside of the flow tube is a brushless DC motor stator which is used to drive the impeller. The overall length (3 inches) and diameter (1 inch) combined with weight of 1.9 ounces (53 grams) demonstrate the extreme small size and compactness of this device (see Figure 3). In the front of the pump is a flow straightener/ bearing holder which is clamped in place by an external clamping ring. It holds the front bearing and prevents prerotation of the fluid entering the pumping region. Spinning on the shaft behind the flow straightener is an inducer. This pump element provides additional fluid pressure to the impeller and improves overall system efficiency. Behind the inducer is the impeller with magnets imbedded in the blades. Fixed behind the impeller in the same fashion as the front flow straightener is the flow stator. This element holds the rear bearing and changes the swirling flow generated by the impeller to an axial flow.

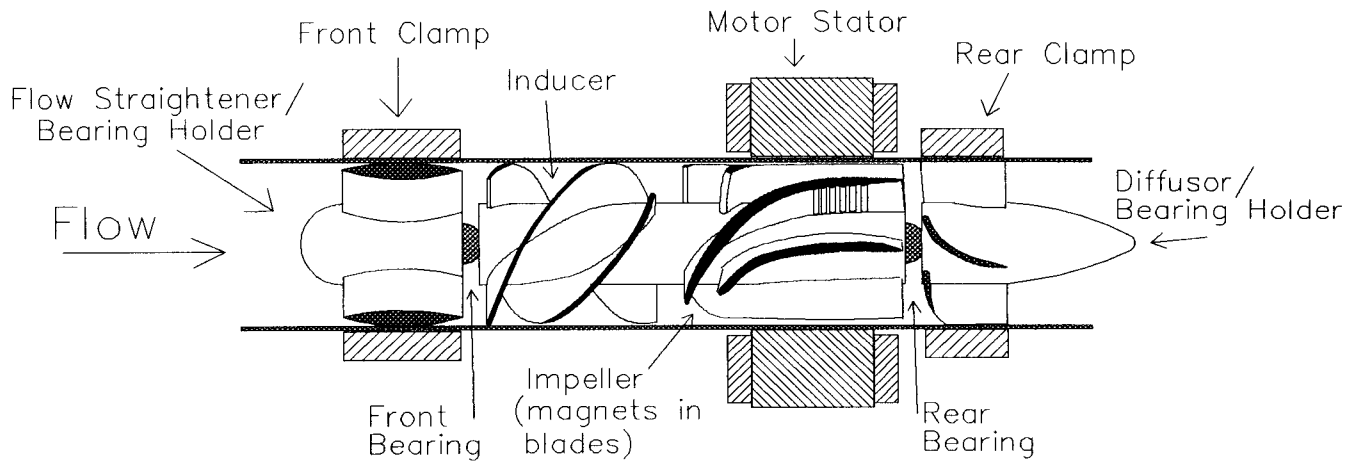


Figure 3. Schematic of the NASA/Baylor Axial flow Pump

In order to provide rapid turn-around during this development phase, the internal pump components are manufactured from a polyurethane base plastic. Using a technique known as stereolithography, the time between the realization of an idea and actual testing in a pump is greatly reduced. Three implantable axial pumps have been fabricated and tested during the progress of the current funding period.

2.2 In Vitro Performance

In vitro performance of this axial pump was conducted utilizing a standard Baylor in vitro performance test system.¹³ Large improvements in both hydraulic and motor efficiency were achieved during this study period. The brushless DC motor currently in use was developed by Inland Motor and is presently yielding an efficiency of 45% (See Figure 4). This motor design is the first iteration of a three step design process by the motor manufacturer. The goal of 70% motor efficiency can be easily obtained within the near future.

The use of a flow inducer is a new introduction to the implantable axial flow pump. The hydraulic efficiency of the implantable pump has improved by 50% as a result of the flow inducer (See Figure 3). The use of a flow inducer was suggested by NASA engineers at Ames Research Center as a result of analysis by computer flow modeling. An added benefit is the increased pressure that the pump can generate at reduce flows (See Figure 5). This allows the inducer and impeller to spin at lower RPM's to achieve the target pumping rate of 5 L/min against 100 mm Hg.

2.3 In Vitro Hemolysis Tests

In vitro hemolysis tests were conducted utilizing a standard Baylor hemolysis test setup.¹¹ In the past, the Index of Hemolysis (I.H.) for clinically acceptable axial pumps was in the range of 0.04 to 0.06 grams of liberated hemoglobin/100 L blood pumped. The current Index of Hemolysis has

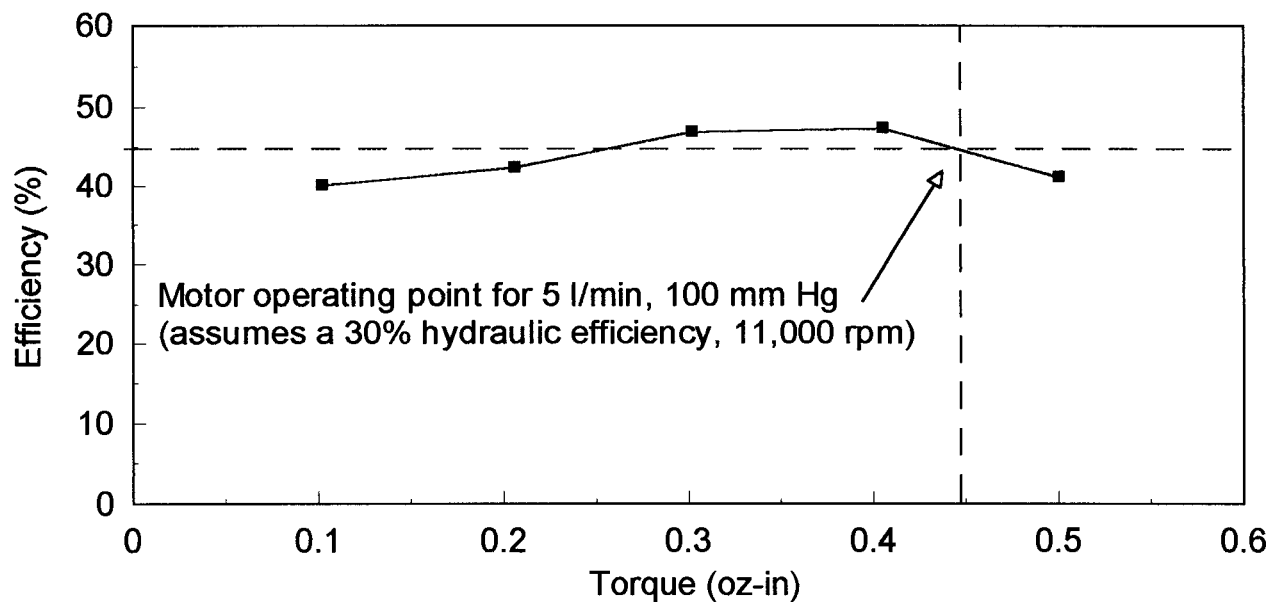


Figure 4. Graph of motor efficiency versus torque.

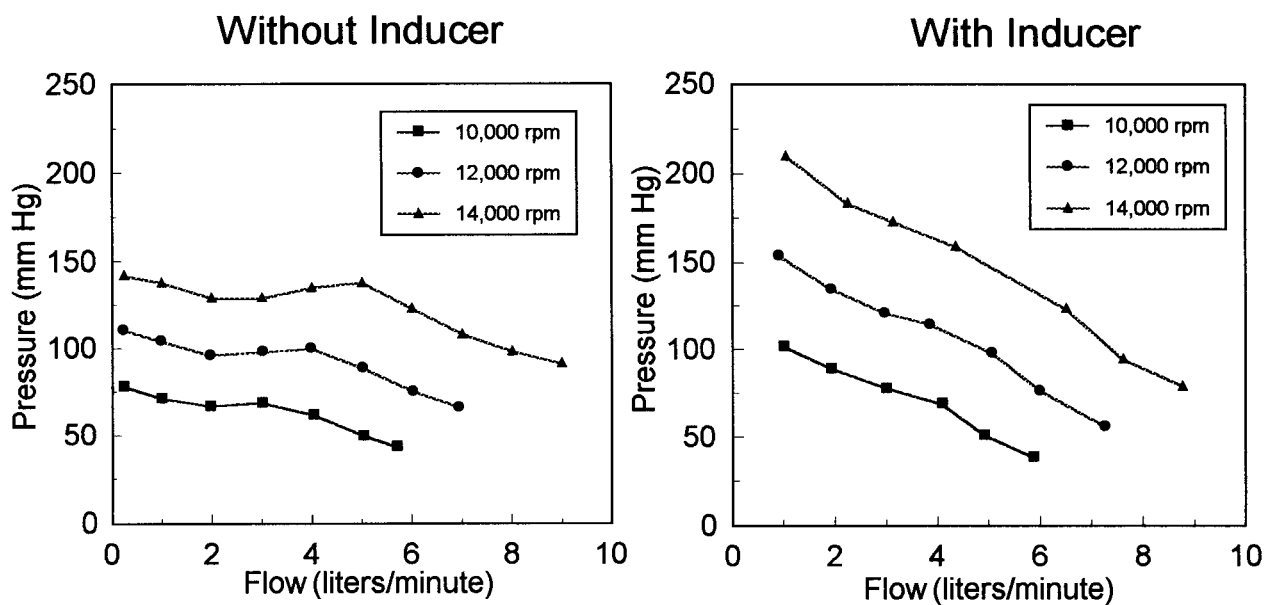


Figure 5. Flow/Pressure curves showing the benefits of inducer on axial pump.

been reduced to 0.021 g/100 L. This level of plasma free hemoglobin is well below physiologically tolerable levels. This represents a 50% reduction from the level achieved with the axial pump prototype and is due mainly to the use of an inducer. In addition to changing the flow field in the pump, the inducer allows a lower RPM for a flow of 5L/min against 100 mm Hg. Other studies have shown a correlation between reduced RPM and reduced hemolysis. Based on studies already conducted, it is expected that the I.H. will be further reduced.

2.4 Endurance Tests

In order to evaluate the pump's endurance characteristics, endurance tests were performed using a water/glycerin blood analog. Various bearing materials were tested. As a result of these tests it was found that the best bearings to absorb the thrust load in the front of the impeller consist of a zirconia ball riding in a sapphire v-ring. The rear bearing only supports radial loads. The most promising configuration consists of a 440C hardened stainless steel shaft riding inside of a sapphire jewel hole. Figure 6 shows a schematic of this configuration.

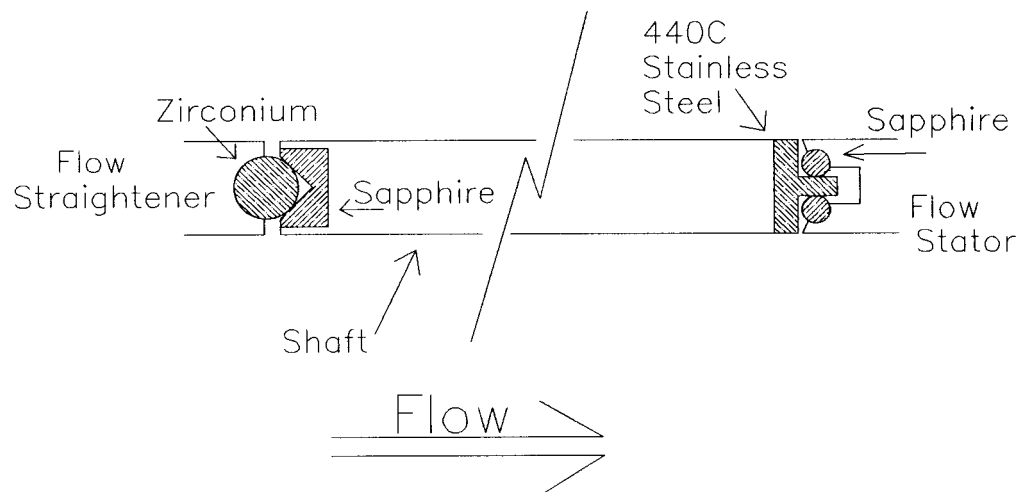


Figure 6. Bearing configuration for axial flow pump.

2.5 In Vivo Feasibility Tests

The goal of the initial in vivo testing done at this stage pump development was to provide a pump capable of lasting two days implanted in an animal. An extracorporeal implant done at Baylor has already achieved that goal. Valuable information was learned in the process. The intent of these experiments was to discover regions in the pump which would lead to thrombus formation. The bearings were found to seed the growth of thrombus and additional studies are necessary. An extremely smooth surface finish on the internal pump components were found to be necessary to minimize thrombus formation. Finally, the implanted magnets are composed of a material which must be passivated or coated to stop the corrosive effects of blood. Left untreated, these magnets

will quickly rust, resulting in a surface which forms thrombus. These magnets will also swell and cause a distorted pump geometry which may lead to pump failure.

2.6 Summary of Current Status

Since the inception of the NASA funding (February, 1993) a great deal of progress has been made toward the final goal of a three month implantable axial flow VAD. The overall efficiency including the motor and hydraulic element of the pump has increased by 50%. As a result, power consumption required to pump 5 L/min against 100 mm Hg has dropped below 10 Watts, 35% below that reported by other leading axial pump groups.²⁴ The Index of Hemolysis has been reduced to 0.021 g/100 L, well below the targeted level of 0.04 g/100 L. Continued endurance testing has led us to bearing materials which can function with minimal wear. Finally, the initial in vivo studies have successfully achieved an implant of two days. From these in vivo studies, much information has been learned which will be applied towards the further refinement of the pump. Among these important areas are bearing configuration, pump surface quality and magnet protection. Based upon this feasibility study, the NASA/Baylor team proved the suitability of this axial flow ventricular assist device (VAD). Now, we are ready to propose this three year program to assure the successful achievement of our objective.

3.0 Program Outline

3.1 Program, Phase 1

The goal of this project during the first year of funding, September 1, 1993 through August 31, 1994 is to achieve an implant of the axial flow pump in a calf lasting longer than two days. Work will be done to eliminate or reduce thrombus formation in the pump. Additional in vivo tests are planned which will use the axial flow pump as a cardiopulmonary bypass pump, using the oxygenator as a reservoir. These tests will enable initiation of the FDA approval process (510 K) starting the second year of the program.

Throughout the course of this funding period, additional hemolysis testing will be performed as design changes require to evaluate the pumps antihemolytic nature. Endurance testing will continue in order to identify possible pump features requiring redesign. Overall pump efficiency will be increased. Hydraulic efficiency will be improved by both empirical methods and analytical means using computer flow modeling. Motor efficiency will be increased as the design iterations continue and the motor and electronic systems are improved. In addition, efforts will be made to investigate metals and other materials which might be used to create a better blood compatible surface.

3.2 Program, Phase 2

During Phase 2, September 1, 1994 through August 31, 1995, the goal is to achieve an implant in a calf of at least two weeks duration. Concurrently, a 510K application will be filled with the FDA. 510K approval is given by the FDA for the device which has a similar safety and efficacy as devices already approved by the FDA. Application of the axial flow pump towards postcardiotomy cardiac failure patients and those requiring extracorporeal membrane oxygenators (ECMO) will also be investigated using the appropriate animal models. As in Phase 1, engineering on the pump will continue with the goal of increasing system efficiency and decreasing hemolysis and thrombus formation.

3.3 Program, Phase 3

September 1, 1995 through August 31, 1996 marks Phase 3. During this period, the goal is to achieve an implant of greater than two weeks duration. The final goal is to successfully implant a pump longer than three months duration. After completion of this three year program, an Investigational Device Exemption (IDE) will be applied to the FDA for clinical application of the NASA/Baylor VAD. The IDE is the required approval process by the FDA for new clinical devices which are introduced as original devices. Together with institutional approval, we can apply the new device (NASA/Baylor VAD) for clinical cases.

4.0 Program Detail, (Experimental Method, Phase 1)

Throughout this proposed program, the following tasks will be conducted:

4.1 Design and Fabrication of the NASA/Baylor Axial Pump

Based upon work conducted at Baylor College of Medicine, Department of Surgery and NASA/JSC, the following pump parameters have been defined (See Table 1). The overall length is 3 inches, the diameter is 1 inch and the weight is 1.9 ounces.

Table 1. Axial Pump Design Parameters

Parameter	Pump Components			
	Flow Straightener	Inducer	Impeller	Diffuser
Entrance Angle (degrees)	90°	10°	15°	15°
Outlet Angle (degrees)	90°	20°	90°	90°
Max Blade Thickness (inches)	0.030"	0.035"	0.07"	0.04"
Axial Clearance (inches)				
Radial Clearance (inches)	0	0.005"	0.005"	0
Geometry	NACA [□]	Drawing*	Drawing*	Drawing*
Length (inches)	0.30"	0.40"	0.675"	0.30"
Wrap (degrees)	N/A°	240°	N/A	N/A
Number of Blades	4	3	6	6
Overlap (degrees)	N/A	120°	N/A	N/A

[□] Conforms to NACA specifications

* See Figure 3

Each impeller has 8 small NdFeB-35 (rare earth) magnets inserted into each blade. These magnets are 0.05" in diameter and 0.15" in length. The bearing configuration is see in Figure 6. Additional pumps will be fabricated using these design rules. With these parameters, the axial pump can produce 5 L/min against 100 mm Hg drawing less than 10 watts of power. It produces an Index of Hemolysis of 0.021 g/100L. As the need warrants, the design will be modified to decrease thrombus formation and hemolysis and increase hydraulic efficiency and performance.

4.2 In Vitro Performance

In vitro performance of this axial pump will be conducted utilizing a standard Baylor in vitro performance test system.¹³ The required RPM to pump a flow of 5 L/min against a total pressure head of 25, 50, 75, 100, 125, and 150 mmHg, will be measured. An iterative process will be utilized to increase hydraulic efficiency and performance. Currently the hydraulic efficiency is 30%. Turbine design engineers at NASA/Johnson Space Center and computer flow modellers at NASA/Ames Research center will alter the design and test the results empirically in the in vitro test system. The same technique will be used to increase the performance of the brushless DC motor used to drive the axial pump. Inland Motor of Radford, Virginia has been contracted to improve the motor efficiency. After their first iteration, a motor efficiency of 45% has been achieved (see Figure 4). Two more iterations are planned and it is expected to result in a motor efficiency of approximately 70%.

4.3 In Vitro Hemolysis Test

In vitro hemolysis tests will be conducted utilizing a standard Baylor hemolysis test setup.⁶ Tests will be performed utilizing fresh calf blood. Currently the axial pump produces an Index of Hemolysis of 0.021 g/100 L. This level is expected to be decreased as the hydraulic efficiency improves and the design of the impeller is modified.

4.4 Endurance Tests

Endurance tests initiated during the period of initial NASA funding will continue. Endurance tests will performed using a water/glycerin blood analog at elevated temperatures (42°C). Under this condition, life expectance is expected to be reduced compared to testing under physiological conditions. Additional bearing studies will be performed to improve the wear properties of the bearing system. Magnet corrosion studies will be conducted in order to determine the optimal coating, passivation or encapsulation methods.

4.5 In Vivo Studies

As previously mentioned, the goal of the first year of this program is to achieve an implant in a calf lasting longer than 2 days. Specifically, several in vivo test series are planned.

Table 2. In vivo studies.

In vivo Studies, Phase 1		
Number of Studies	Procedure	Duration
8	Calf Implant (Including Cardiopulmonary Bypass)	2 days
6	Calf Implant	2 weeks
3	Calf Implant	4 weeks

There are several goals for each calf implant. Thrombus formation in the pump is a critical issue which will be addressed by the implants. At the conclusion of each test, both front and rear bearings and the surfaces of the interior components of the pump will be examined for thrombus formation. Design changes will be implemented as a result of these findings to eliminate their formation. Changes will include bearing materials and configurations, pumping element materials and configuration and any other alterations which may be required. The anatomical configuration of the implanted pump will also be evaluated. The optimal placement of the device in vivo will be determined. This includes the placement of both inflow and outflow cannulae and position of the pump. At the termination of each animal experiment, detailed histopathological studies will be conducted searching for any thrombus in the vascular system.

4.6 Progress Report

After completing each funding period of the study, a progress report will be submitted.